since the House passed a COVID relief bill, a bill that would put money in the pockets of workers, up to $6,000 per household; it would extend unemployment benefits for those people who have lost their jobs as a result of this pandemic; and it would support small businesses, importantly, those small businesses that are just on the brink of failure, to ensure that relief gets to those underserved communities and especially to some of our nonprofits.

Sadly, the COVID bill sits on MITCH MCCONNELL's desk, gathering dust.

This is a pandemic. It is a health crisis. It is an economic crisis. We need to come together, put politics aside, negotiate with one another, come to a compromise, and help the American people.

## RECOGNIZING VETERANS DAY

(Mr. MURPHY of North Carolina asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. MURPHY of North Carolina. Mr. Speaker, this past Wednesday, we recognized Veterans Day.

It is most appropriate that we set aside a day each year to thank the brave men and women in our Armed Forces who have selflessly sacrificed so much for our great Nation.

For more than two centuries, Americans have fought under the American flag for the principles of freedom, justice, and equality under the law.

Our Americans stand tall and are respected worldwide for their dedication to country and the sacrifices that they have made for our freedom. Many have gone to hell and back to preserve the natural rights outlined in the Constitution, specifically freedom of speech, freedom of religion, and the right to bear arms.

In eastern North Carolina, I am honored to represent 95,000 veterans, the third most of any congressional district in the United States.

Despite the partisanship oftentimes seen in this body, it is critical, like was done on this House floor last night, that we show broad, bipartisan support for our American veterans.

Their defense of our Nation has not been just for Democrat, not just for Republican or independent. It has been for all Americans.

So, again, we say thank you for your service, and God bless you all.

## CREDITING OPERATION WARP SPEED

(Mr. WILSON of South Carolina asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. WILSON of South Carolina. Mr. Speaker, with America under attack by the Wuhan virus, President Donald Trump announced Operation Warp Speed, led by Vice President MIKE PENCE.

Operation Warp Speed is America's commonsense path toward a historic effort to safely bring the virus testing, treatments, and vaccines to the American people in record time.

Extraordinary scientists, doctors, and manufacturers from around the Nation are working tirelessly through Operation Warp Speed to develop safe and effective vaccines. A safe, effective vaccine is the key to restoring our normal way of life and restoring jobs.

Just this week, Moderna announced vaccine success and, thanks to President Trump, vaccine production is underway.

This is great news for our families and for the restoration of jobs, and I am grateful that we are closer than ever to defeating the pandemic.

In conclusion, God bless our troops, and we will never forget September 11th in the global war on terrorism.

## REMEMBERING HUGH PENDLETON NUNNALLY, JR.

(Mr. CARTER of Georgia asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. CARTER of Georgia. Mr. Speaker, I rise today in remembrance of Hugh Pendleton Nunnally, Jr., who was a pillar in the Golden Isles community.

Hugh was born and raised in Atlanta and graduated from Georgia Tech with a degree in agriculture. After graduating, he was fortunate enough to be mentored by Malon Courts of the Courts & Company and became a broker within 2 years.

In 1955, he was drafted into the Army and finished his service in 1957 as a sergeant.

Following Hugh's time in the Army, he became a founding partner in the brokerage firm Budd & Company and then a founding partner of Presidential Financial Company.

After the death of his precious wife, Miriam, he was devoted to many philanthropic efforts, including the Southeast Georgia Health System, the Nunnally House, the College of Coastal Georgia, the Humane Society of South Coastal Georgia, and the Hospice of the Golden Isles.

Hugh will always be remembered for his endearing smile, compassion, and selflessness.

My thoughts and prayers are with all who knew and loved him during this most difficult time.

## ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on motions to suspend the rules on which the yeas and nays are ordered.

The House will resume proceedings on postponed questions at a later time.

## NIMHD RESEARCH ENDOWMENT REVITALIZATION ACT OF 2020

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4499) to amend the Public Health Service Act to provide that the authority of the Director of the National Institute on Minority Health and Health Disparities to make certain research endowments applies with respect to both current and former centers of excellence, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 4499

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''NIMHD Research Endowment Revitalization Act of 2020''.

**SEC. 2. RESEARCH ENDOWMENTS AT BOTH CURRENT AND FORMER CENTERS OF EXCELLENCE.**

Paragraph (1) of section 464z–3(h) of the Public Health Service Act (42 U.S.C. 285t(h)) is amended to read as follows:

''(1) IN GENERAL.—The Director of the Institute may carry out a program to facilitate minority health disparities research and other health disparities research by providing for research endowments—

''(A) at current or former centers of excellence under section 736; and

''(B) at current or former centers of excellence under section 464z–4.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Oregon (Mr. WALDEN) each will control 20 minutes.

The Chair recognizes the gentleman from New Jersey.

GENERAL LEAVE

Mr. PALLONE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on H.R. 4499.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New Jersey?

There was no objection.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

I rise today in support of H.R. 4499, the NIMHD Research Endowment Revitalization Act of 2020.

This bill authorizes the National Institute on Minority Health and Health Disparities, or NIMHD, to facilitate research on minority health disparities through research endowments at current or former Centers of Excellence.

The NIMHD Research Endowment Program was established by the Minority Health and Disparities Research and Education Act of 2000. By supporting the endowments of certain academic institutions, the program promotes minority health and health disparities research capacity, increases the diversity of the scientific workforce, and enhances the recruitment and retention of underrepresented individuals in science.

Congress expanded the eligibility of the program to include institutions of higher education with an active NIMHD Center of Excellence, and this expansion inadvertently resulted in

schools such as Morehouse School of Medicine, Georgia State University, and Morgan State University being ineligible.

As our Nation continues to combat the COVID–19 pandemic, there is an even more urgent need to support additional research into minority health and health disparities, and to bolster the recruitment and retention of underrepresented individuals in science.

Mr. Speaker, I commend the lead sponsors, Representatives BARRAGÁN, CARTER, and the late John Lewis, and their staffs, for their work on this legislation. I also thank the Democratic and Republican members of our committee, as well as bipartisan committee staff, for working together to move this bill.

Mr. Speaker, I urge my colleagues to support H.R. 4499, and I reserve the balance of my time.

Mr. WALDEN. Mr. Speaker, I yield myself such time as I may consume.

I, too, rise in support of H.R. 4499, the National Institute on Minority and Health Disparities Research Endowment Revitalization Act.

Mr. Speaker, I thank my Committee on Energy and Commerce colleagues on both sides of the aisle, especially Congressman CARTER and Congresswoman BARRAGÁN, for their leadership on this bill, and the chairman for moving it.

This bill authorizes the National Institute on Minority Health and Health Disparities to award research grants to current and former Centers of Excellence that conduct research on minority health disparities.

Health inequalities and inequities are disproportionately experienced by minority populations, and we all know they can have adverse impacts on health outcomes, on economic opportunities and, frankly, on overall quality of life. The COVID–19 pandemic has exacerbated these disparities, which is why this legislation is so important, Mr. Speaker.

Continued support of these Centers of Excellence is critical in advancing minority health, addressing health inequities, and expanding educational and training opportunities for those interested in further advancing research in this space.

Mr. Speaker, I urge my colleagues to support this important legislation, and I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I have no additional Members who would like to speak on the bill, and so I urge support for the legislation. I yield back the balance of my time.

Mr. WALDEN. Mr. Speaker, I yield 2 minutes to the gentleman from Ohio (Mr. LATTA).

Mr. LATTA. Mr. Speaker, I thank the gentleman very much for yielding.

Mr. Speaker, I rise today in support of H.R. 4499, the NIMHD Research Endowment Revitalization Act of 2020.

This is an extremely important piece of legislation, and I intend to support it.

I also intend to ask the House today to support my legislation, which is H.R. 4806, the Debarment Enforcement of Bad Actor Registrants Act of 2019, or the DEBAR Act.

Substance abuse continues to wreak havoc in our communities and is responsible for claiming nearly 700,000 lives since 1999. In the first quarter of this year alone, overdose death rates increased 11.4 percent compared to the same time last year.

As we work to put an end to the coronavirus pandemic, addressing the ongoing opioid epidemic is increasingly critical.

□ 1215

I introduced the DEBAR Act because it takes significant steps to reduce the circulation of illegal substances in our country.

This bill provides the Drug Enforcement Agency debarment authority to permanently prohibit a person or entity who has violated the Controlled Substances Act from being able to receive a registration to manufacture, distribute, or dispense a controlled substance.

We cannot stop our efforts to end the opioid and substance abuse crisis, and I encourage my colleagues to support H.R. 4806 and H.R. 4499.

I also want to thank the chairman for his work on both of these pieces of legislation, and the ranking member, and I encourage my colleagues to support both pieces of legislation.

Mr. WALDEN. Mr. Speaker, I yield 2 minutes to the gentleman from Georgia (Mr. CARTER), one of the coauthors of this piece of legislation.

Mr. CARTER of Georgia. Mr. Speaker, I thank the gentleman for yielding.

Mr. Speaker, I am thankful for the time today to speak on this important legislation, and I thank Congresswoman BARRAGÁN for being a champion of this issue.

The coronavirus has wreaked havoc on our communities. Now, more than ever, we must support minority academic institutions and the critical research they conduct. Minority academic institutions can play a big role in conducting critical research and helping us work to lessen the health disparities minority communities face.

We must ensure schools, including the Morehouse College in my home State of Georgia, are able to conduct their research without disruption. Their efforts will better prepare all of us to respond to the coronavirus and other health inequities more effectively.

I urge passage today.

Mr. WALDEN. Mr. Speaker, I don't believe we have any other Members wishing to speak on this legislation, so I will just close and say it is another great work product from our Energy and Commerce Committee, bipartisan legislation that I encourage our colleagues to support, and I yield back the balance of my time.

Ms. BARRAGÁN. Mr. Speaker, I rise today in support of H.R. 4499, the NIMHD Research Endowment Revitalization Act, a bill I introduced with my friend and colleague from Georgia, Congressman CARTER.

This legislation moves us closer to ending the disparities in public health between minority communities and other Americans. We need to understand why people in minority communities are more likely to get certain illnesses and how we can prevent that. H.R. 4499 will fund the research that will help us find solutions.

If signed into law, this bill will once again allow for current and former NIMHD or HRSA Centers of Excellence to receive research endowment funding, money that is critical in the fight to reduce minority health disparities.

The Research Endowment Program at the National Institute on Minority Health and Health Disparities provides funding to the endowments of academic institutions across the country, such as Charles Drew University in my district.

The goals of the program include:

Promoting minority health and health disparities research capacity and infrastructure;

Increasing the diversity and strength of the scientific workforce; and

Enhancing the recruitment and retention of individuals from health disparity populations that are underrepresented in the scientific workforce.

Charles Drew University has stated that this legislation and the funding are critical to their mission and that they support this legislation because:

''Restoring eligibility would allow the University to continue its historic focus on research to close the gap between the burden of illness and premature mortality experienced more commonly by communities of color, as well as other medically underserved populations, as compared to the nation as a whole. It would also help to grow and enhance the University's capacity and infrastructure for health disparities research within the Urban Health Institute.''

During the COVID health emergency, where communities of color are once again disproportionately affected, research into health disparities is more crucial than ever.

I want to once again thank my colleague Congressman CARTER for co-leading this bill with me, as well as the other bipartisan cosponsors: Congresswoman KELLY, Congressman ROGERS, and the late John Lewis. I also want to thank Chairman PALLONE for working with me to help move this important bill through the Committee.

I urge all my colleagues to vote yes on the NIMHD Research Endowment Revitalization Act so that these schools can continue this important research on minority health disparities.

CHARLES R. DREW UNIVERSITY OF MEDICINE AND SCIENCE STATEMENT ON H.R. 4499

Charles R. Drew University of Medicine in Science (CDU) is in strong support of H.R. 4499 which amend the Public Health Service Act to provide that the authority of the Director of the National Institute on Minority Health and Health Disparities to make certain research endowments applies with respect to both current and former centers of excellence, and for other purposes.

If enacted H.R. 4499 would reinstate the University's eligibility for NIMHD endowment grants that were withdrawn because the University had received endowment grants for 10 years despite being underfunded for its critical health disparities research.

Restoring eligibility would allow the University to continue its historic focus on research to close the gap between the burden of illness and premature mortality experienced more commonly by communities of color, as well as other medically underserved populations, as compared to the nation as a whole. It would also help to grow and enhance the University's capacity and infrastructure for health disparities research within the Urban Health Institute.

Respectfully Submitted,
DAVID M. CARLISLE, MD, PhD,
*President and CEO, Charles R. Drew University of Medicine and Science.*

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 4499, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

## MAKING OBJECTIVE DRUG EVIDENCE REVISIONS FOR NEW LABELING ACT OF 2020

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5668) to amend the Federal Food, Drug, and Cosmetic Act to modernize the labeling of certain generic drugs, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5668

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

***SECTION 1. SHORT TITLE.***

*This Act may be cited as the ''Making Objective Drug Evidence Revisions for New Labeling Act of 2020'' or the ''MODERN Labeling Act of 2020''.*

***SEC. 2. MODERNIZING THE LABELING OF CERTAIN GENERIC DRUGS.***

*Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503C the following:*

***''SEC. 503D. PROCESS TO UPDATE LABELING FOR CERTAIN DRUGS.***

*''(a) DEFINITIONS.—For purposes of this section:*

*''(1) The term 'covered drug' means a drug approved under section 505(c)—*

*''(A) for which there are no unexpired patents included in the list under section 505(j)(7) and no unexpired period of exclusivity;*

*''(B) for which the approval of the application has been withdrawn for reasons other than safety or effectiveness; and*

*''(C) for which—*

*''(i)(I) there is new scientific evidence available pertaining to the existing conditions of use that is not reflected in the labeling;*

*''(II) the approved labeling does not reflect current legal and regulatory requirements for content or format; or*

*''(III) there is a relevant accepted use in clinical practice that is not reflected in the approved labeling; and*

*''(ii) updating the labeling would benefit the public health.*

*''(2) The term 'period of exclusivity', with respect to a drug approved under section 505(c), means any period of exclusivity under clause (ii), (iii), or (iv) of section 505(c)(3)(E), clause (ii), (iii), or (iv) of section 505(j)(5)(F), or section 505A, 505E, or 527.*

*''(3) The term 'generic version' means a drug approved under section 505(j) whose reference listed drug is a covered drug.*

*''(4) The term 'relevant accepted use' means a use for a drug in clinical practice that is supported by scientific evidence that appears to the Secretary to meet the standards for approval under section 505.*

*''(5) The term 'selected drug' means a covered drug for which the Secretary has determined through the process under subsection (c) that the labeling should be changed.*

*''(b) IDENTIFICATION OF COVERED DRUGS.—The Secretary may identify covered drugs for which labeling updates would provide a public health benefit. To assist in identifying covered drugs, the Secretary may do one or both of the following:*

*''(1) Enter into cooperative agreements or contracts with public or private entities to review the available scientific evidence concerning such drugs.*

*''(2) Seek public input concerning such drugs, including input on whether there is a relevant accepted use in clinical practice that is not reflected in the approved labeling of such drugs or whether new scientific evidence is available regarding the conditions of use for such drug, by—*

*''(A) holding one or more public meetings;*

*''(B) opening a public docket for the submission of public comments; or*

*''(C) other means, as the Secretary determines appropriate.*

*''(c) SELECTION OF DRUGS FOR UPDATING.—If the Secretary determines, with respect to a covered drug, that the available scientific evidence meets the standards under section 505 for adding or modifying information to the labeling or providing supplemental information to the labeling regarding the use of the covered drug, the Secretary may initiate the process under subsection (d).*

*''(d) INITIATION OF THE PROCESS OF UPDATING.—If the Secretary determines that labeling changes are appropriate for a selected drug pursuant to subsection (c), the Secretary shall provide notice to the holders of approved applications for a generic version of such drug that—*

*''(1) summarizes the findings supporting the determination of the Secretary that the available scientific evidence meets the standards under section 505 for adding or modifying information or providing supplemental information to the labeling of the covered drug pursuant to subsection (c);*

*''(2) provides a clear statement regarding the additional, modified, or supplemental information for such labeling, according to the determination by the Secretary (including, as applicable, modifications to add the relevant accepted use to the labeling of the drug as an additional indication for the drug); and*

*''(3) states whether the statement under paragraph (2) applies to the selected drug as a class of covered drugs or only to a specific drug product.*

*''(e) RESPONSE TO NOTIFICATION.—Within 30 days of receipt of notification provided by the Secretary pursuant to subsection (d), the holder of an approved application for a generic version of the selected drug shall—*

*''(1) agree to change the approved labeling to reflect the additional, modified, or supplemental information the Secretary has determined to be appropriate; or*

*''(2) notify the Secretary that the holder of the approved application does not believe that the requested labeling changes are warranted and submit a statement detailing the reasons why such changes are not warranted.*

*''(f) REVIEW OF APPLICATION HOLDER'S RESPONSE.—*

*''(1) IN GENERAL.—Upon receipt of the application holder's response, the Secretary shall promptly review each statement received under subsection (e)(2) and determine which labeling changes pursuant to the Secretary's notice under subsection (d) are appropriate, if any. If the Secretary disagrees with the reasons why such labeling changes are not warranted, the Secretary shall provide opportunity for discussions with the application holders to reach agreement on whether the labeling for the covered drug should be updated to reflect available scientific evidence, and if so, the content of such labeling changes.*

*''(2) CHANGES TO LABELING.—After considering all responses from the holder of an approved application under paragraph (1) or (2) of subsection (e), and any discussion under paragraph (1), the Secretary may order such holder to make the labeling changes the Secretary determines are appropriate. Such holder of an approved application shall—*

*''(A) update its paper labeling for the drug at the next printing of that labeling;*

*''(B) update any electronic labeling for the drug within 30 days of such order; and*

*''(C) submit the revised labeling through the form, 'Supplement—Changes Being Effected'.*

*''(g) VIOLATION.—If the holder of an approved application for the generic version of the selected drug does not comply with the requirements of subsection (f)(2), such generic version of the selected drug shall be deemed to be misbranded under section 502.*

*''(h) LIMITATIONS; GENERIC DRUGS.—*

*''(1) IN GENERAL.—With respect to any labeling change required under this section, the generic version shall be deemed to have the same conditions of use and the same labeling as its reference listed drug for purposes of clauses (i) and (v) of section 505(j)(2)(A). Any labeling change so required shall not have any legal effect for the applicant that is different than the legal effect that would have resulted if a supplemental application had been submitted and approved to conform the labeling of the generic version to a change in the labeling of the reference drug.*

*''(2) SUPPLEMENTAL APPLICATIONS.—Changes to labeling made in accordance with this section shall not be eligible for an exclusivity period under this Act.*

*''(3) SELECTION OF DRUGS.—Nothing in this section shall be construed to give the Secretary the authority to identify a drug as a covered drug or select a drug label for updating solely based on the availability of new safety information. Upon identification of a drug as a covered drug, the Secretary may then consider the availability of new, additional, or different safety information in determining whether the drug is a selected drug and in determining what labeling changes are appropriate.*

*''(4) MAINTENANCE OF LABELING.—Nothing in this section shall be construed to affect the responsibility of the holder of an approved application under section 505(j) to maintain its labeling in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 314.97 of title 21, Code of Federal Regulations (or any successor regulations).*

*''(i) RULES OF CONSTRUCTION.—*

*''(1) APPROVAL STANDARDS.—This section shall not be construed as altering the applicability of the standards for approval of an application under section 505. No order shall be issued under this subsection unless the scientific evidence supporting the changed labeling meets the standards for approval applicable to any change to labeling under section 505.*

*''(2) SECRETARY AUTHORITY.—Nothing in this section shall be construed to limit the authority of the Secretary to require labeling changes under section 505(o).*

*''(j) REPORTS.—Not later than 4 years after the date of the enactment of the Making Objective Drug Evidence Revisions for New Labeling Act of 2020, and every 4 years thereafter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, a report that—*